

# EXHIBIT 16



Appln. No.: 14/103,324  
Amendment Dated November 4, 2015  
Reply to Office Action of August 10, 2015

TEVE-139US1

**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**

Appln. No.: 14/103,324  
Applicant: Declan Walsh et al.  
Filed: December 11, 2013  
Title: DOSE COUNTERS FOR INHALERS, INHALERS AND METHODS OF  
ASSEMBLY THEREOF  
T.C./A.U.: 2876  
Examiner: Daniel A. Hess  
Confirmation No.: 3830  
Docket No.: TEVE-139US1

**AMENDMENT**

Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

Commissioner:

Responsive to the Office Action dated August 10, 2015, please amend the above-identified application as follows:

- ☐ **Amendments to the Specification** begin on page \_\_\_\_\_ of this paper.
- ☒ **Amendments to the Claims** are reflected in the listing of claims which begins on page 2 of this paper.
- ☐ **Amendments to the Drawings** begin on page \_\_\_\_\_ of this paper and include an attached replacement sheet(s).
- ☐ **Amendments to the Abstract** are on page \_\_\_\_\_ of this paper. A clean version of the Abstract is on page \_\_\_\_\_ of this paper.
- ☒ **Remarks/Arguments** begin on page 4 of this paper.



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**Amendments to the Claims:** This listing of claims will replace all prior versions and listings of claims in the application.

Listing of Claims:

1. (Currently Amended) An inhaler for metered dose inhalation, the inhaler comprising a main body having a canister housing, ~~arranged to retain a medicament canister retained in the canister housing and movable relative thereto for motion therein,~~ and a dose counter, the dose counter having an actuation member having at least a portion thereof located in the canister housing for operation by movement of ~~a~~ the medicament canister, wherein the canister housing has an inner wall, and a first inner wall canister support formation extending inwardly from a main surface of the inner wall and located directly adjacent the actuation member.
2. (Currently Amended) The inhaler as claimed in claim 1 ~~which has a~~ wherein the medicament canister ~~mounted thereto is~~ movable relative to the dose counter.
3. (Original) The inhaler as claimed in claim 1 further comprising an aperture formed in the inner wall through which the portion of the actuation member extends.
4. (Original) The inhaler as claimed in claim 1, wherein the first inner wall canister support formation comprises a support rail which extends longitudinally along an inside surface of the main body.
5. (Original) The inhaler as claimed in claim 4, wherein the support rail includes a step formed thereon.
6. (Original) The inhaler as claimed in claim 4 further comprising a plurality of support rails each of which extends longitudinally along an inside surface of the main body.
7. (Original) The inhaler as claimed in claim 6, wherein two of the plurality of support rails are positioned at opposite ends of the inside surface of the main body to face each other.
8. (Original) The inhaler as claimed in claim 4, wherein the support rail includes two steps formed thereon, the steps being spaced apart longitudinally along an inside surface of the main body.
9. (Original) The inhaler as claimed in claim 4, wherein the support rail merges with the inner wall at a location adjacent the aperture.



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10. (Original) The inhaler as claimed in claim 9, wherein a width dimension of the support rail is not constant, and the width dimension is greatest at the location where the support rail merges with the inner wall.

11. - 20. (Cancelled)



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**Remarks/Arguments:**

**Claim Status**

Claims 1-10 are pending and stand rejected. Claims 1 and 2 have been amended. Claims 11-20 have been cancelled without prejudice or disclaimer of the subject matter thereof. No new matter has been added.

**Claim Rejections – 35 USC § 102/103**

Claims 1-10 are rejected under pre-AIA 35 U.S.C. 102(b) as anticipated by or, in the alternative, under pre-AIA 35 U.S.C. 103(a) as obvious over Morton (US 2005/0087191). Also, claims 1-3 are rejected under pre-AIA 35 U.S.C. 103(a) as being unpatentable over Davies (US 2006/0107949). The Applicant respectfully requests reconsideration of these rejections for the reasons set forth hereinafter.

"A claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference." M.P.E.P. §2131 *citing Verdegaal Bros. v. Union Oil Co. of California*, 814 F.2d 628, 631, 2 USPQ2d 1051, 1053 (Fed. Cir. 1987). In establishing a prima facie case of obviousness, "all of the claim limitations must be considered." M.P.E.P. §2143. Independent claim 1 recites features that are neither disclosed nor suggested by the cited references, namely:

**... a medicament canister retained in the canister housing and movable relative thereto**, and a dose counter, the dose counter having an actuation member having at least a portion thereof located in the canister housing for operation by movement of the medicament canister, wherein the **canister housing has an inner wall, and a first inner wall canister support formation extending inwardly** from a main surface of the inner wall and located directly adjacent the actuation member. [Emphasis added]

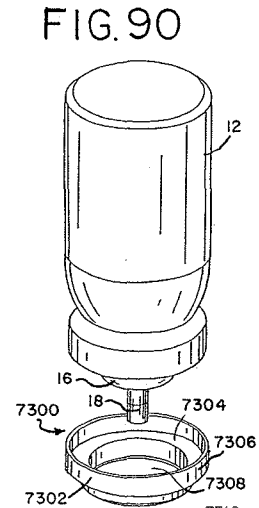


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***Morton (US 2005/0087191)***

Claim 1 has been amended to recite that the medicament canister is moveable relative to the canister housing and, consequently, the inner wall thereof and the canister support formation. The Office Action relies on item 7300 in Fig. 90 of Morton (see right) for disclosure of a canister support formation. In contrast to the limitations of claim 1, the key member 7300 of *Morton* is attached to its container 12 in such a way that it moves with the container, not "relative" to the container, as is required of the support formation of amended claim 1.



Paragraph [0297] of Morton recites (with emphasis added and the addition of "[12]"):

*[0297] Now referring to FIGS. 90-92, a key member 7300 is shown as including a base portion 7302 having a recess 7304 shaped to receive the top of the container [12]. The base portion is circular shaped and is open in the middle. The key member is mounted on the container [12] by **press fitting** a circumferential flange 7306, which forms the recess, about the container such that the valve stem and hub passes through an opening 7308 formed in the middle of the key member. Alternatively, the key member can be mounted to the container [12] with **adhesive or other fasteners**. The key member also includes a key portion 7310 extending downwardly from the base portion. The key portion is preferably configured as a circular flange member, although other shapes would also work.*

Thus, the key member 7300 of *Morton* is attached to its container 12 in such a way that it moves with the container, not relative to the container as required of the first inner wall canister support formation that is recited in amended claim 1. Accordingly, Morton neither discloses nor suggest every feature of claim 1.



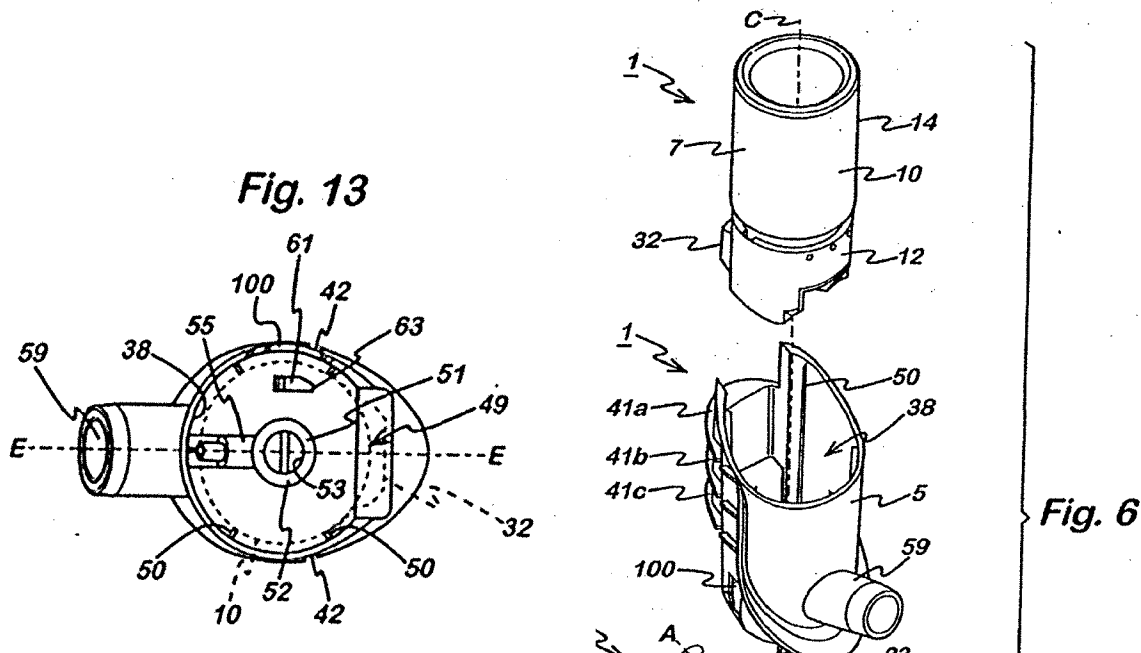
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**Davies (US 2006/0107949)**

As noted above, claim 1 has been amended to recite "wherein the canister housing has an inner wall, and a first inner wall canister support formation extending inwardly from a main surface of the inner wall and located directly adjacent the actuation member."

The Office Action does not identify which features of Davies' housing are analogous to the claimed canister support formation, however, the Applicant acknowledges that Davies does disclose in paragraph [0080] "*longitudinal spacers 50 arranged circumferentially about the inner surface of the cavity 38 so that the canister unit 7 is generally co-axially mounted in the inner actuating part 5.*" See also Figs. 13 and 6 reproduced below. It is clear from Fig. 13 of Davies, however, that the longitudinal spacers 50 approach the canister (shown in Fig. 13 in broken lines) but are spaced apart from the post 61.



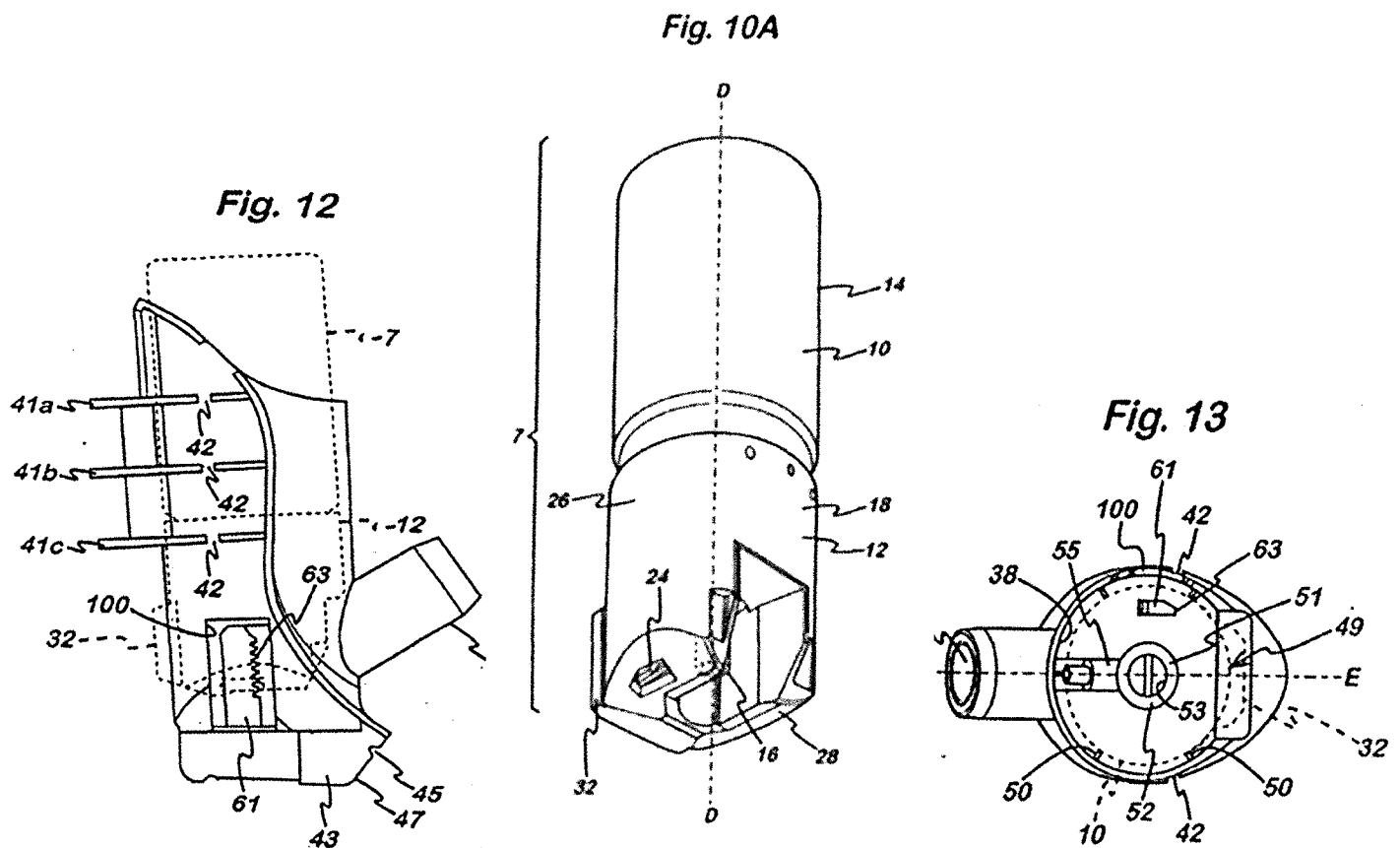
The advantages of the claimed "first inner wall canister support formation" are described in the instant application. As outlined in the paragraph at page 11, lines 16-20 of the instant application, as filed, the arrangement of the invention has been found to be highly advantageous because it prevents the canister from rocking too much relative to the main body of the inhaler in the direction towards the actuation member, thereby substantially improving dose counting and avoiding counter errors.



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A person of ordinary skill in the art would not have arrived at the solution provided by the present invention having read *Davies* because *Davies* makes no connection between the position of inner wall support formations and the performance of the counter. Consequently, there would be no reason whatsoever for the skilled person to even consider altering the position of *Davies*' longitudinal spacers 50, let alone select the specific arrangement required by the present claims.



Furthermore, with reference to the figures above, extending *Davies*' longitudinal spacers 50 inwardly so that they are directly adjacent to the post 61 would not have been obvious because in doing so the longitudinal spacer 50 would engage with the outer wall of the counter 12, thereby obstructing the counter from entering the inhaler and the post 61 from entering the aperture 24.



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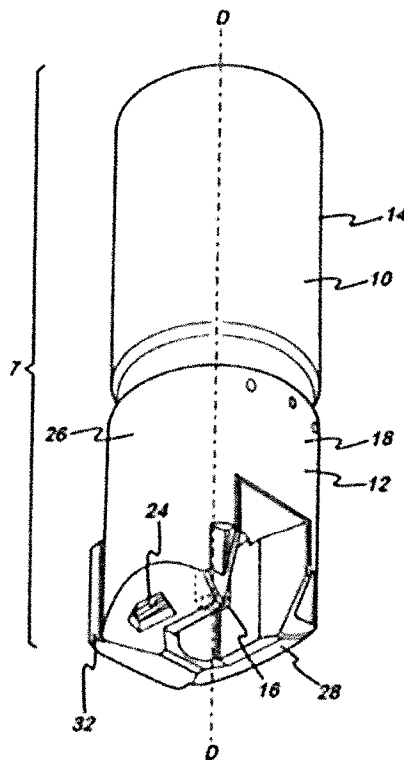
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In the absence of any reason to do so it cannot be obvious to modify *Davies* in such a way that it did not work. Accordingly, the skilled person would not have arrived at the subject matter of claim 1 in view of *Davies*.

Accordingly, because claim 1 includes features that are neither disclosed nor suggested by the cited references, neither anticipation nor *prima facie* obviousness can be established based on the cited references. The dependent claims that stand rejected should also be allowed at least as being dependent upon an allowable base claim. Reconsideration of claims 1-10 is respectfully requested.

Furthermore, dependent claim 2 recites "wherein the medicament canister is movable relative to the dose counter," whereas *Davies*' medicament canister 10 is integral with the dose counter 12, thus, those components cannot move relative to each other.

**Fig. 10A**





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**Conclusion**

In view of the remarks set forth above, the Applicant respectfully submits that this application is now in condition for allowance, which action is respectfully requested. If the Examiner believes an interview will advance the prosecution of this application, it is respectfully requested that the Examiner contact the undersigned to arrange the same.

Respectfully submitted,



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BJR/mf

Dated: November 4, 2015

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The Director is hereby authorized to charge or credit Deposit Account No. **18-0350** for any additional fees, or any underpayment or credit for overpayment in connection herewith.

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